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JUN 15 2001

510(K) SUMMARY OF SAFETY & EFFECTIVENESS

A. K NUMBER : K011262

B. SPONSOR IDENTIFICATION:

NewDeal SA
Parc d'Activités Garigliano
Rue de la Convention
38 200 VIENNE
FRANCE

Tél. : (33) 4 74 78 15 15
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C. ESTABLISHMENT REGISTRATION NUMBER: 9615741

D. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.,
9109 Copenhaver Drive
Potomac, MD 20854

Tel. : (301) 279 -2899
Fax : (301) 294-0126

E. DATE OF PREPARATION OF THIS SUMMARY: April 23, 2001

F. PROPRIETARY (TRADE) NAME: BOLD® SCREW

G. COMMON NAME: Bone fixation screw
Cannulated compression screw

H. CLASSIFICATION NAME AND REFERENCE

Smooth or threaded metallic bone fixation fastener (21 CFR, Section 888.3040)

I. PROPOSED REGULATORY CLASS: Class II

J. DEVICE PRODUCT CODE: 87HWC

K. PANEL CODE: 87OR

L. DESCRIPTION OF DEVICE:

The **BOLD® SCREW** is a cannulated screw made of a Titanium alloy. Its design includes a non threaded shaft and a self-tapping screw tip. Screws come in lengths of 10-34 mm.

M. INTENDED USE: The **BOLD® SCREW** is intended to be implanted for fixation of bone fractures or for bone reconstructions.

N. INDICATIONS FOR USE:

The “new” **BOLD® SCREW** is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of small bone fragments, in long bones or small bones fractures.
- Arthrodesis in hand or foot surgery
- Mono or Bi-cortical osteotomies in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

O. PREDICATE DEVICE: The “new” **BOLD® SCREW** is technically equivalent to the **BOLD®** screw currently approved (K990622). The “new” **BOLD® screw** is substantially equivalent to the Scarf Thread-head Screw (DePuy) (K931155) and the Herbert-Whipple Bone Screw (Zimmer) (K792022)

P. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The “new” **BOLD® screw** is technically equivalent to the device currently approved. They have the same intended use, and the design has not changed.

The “new” **BOLD® screw**, the Scarf Thread-head Screw and the Herbert-Whipple Bone Screw have the same intended use and all are indicated for fixing small fractures or osteotomies.

All are made from Titanium alloys. The **BOLD® SCREW**, the Herbert-Whipple and the Scarf Thread-head Screw have a non-threaded segment. The thread pitch of the Scarf screw differs slightly while the **BOLD® SCREW** has a double pitch at the tip of the screw compared to the head. Both have a thread head and a hexagonal socket. The Scarf Thread-head Screw, the **BOLD® SCREW** and the Herbert-Whipple screw are all cannulated and are topped with a hexagonal socket.

Q. SUMMARY OF STUDIES: The rupture torque of the “new” **BOLD® SCREW** is the same as for the device currently approved, as the design has not changed.

In summary, the “new” **BOLD® screw** has the same technological characteristics (same design, same material, same manufacturing process...) as the device currently sold.

Both devices have the same intended use, both being “intended for fixation of bone fractures or for bone reconstructions”.

The only difference is that the “new” **BOLD® screw** has broader indications for use as the device currently approved. It should however be noticed that the “new” **BOLD® screw** has the same indications for use as the other devices considered as “predicates”.

The impact on Safety and Effectiveness was reevaluated in the “Clinical data” section of this submission. We conclude that no new concerns about Safety and Effectiveness would be raised by extending the indications for use as noted above.



JUN 15 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NewDeal S.A.
c/o Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K011262
Trade Name: The Bold Screw
Regulation Number: 888.3040
Regulatory Class: II
Product Codes: HWC
Dated: April 20, 2001
Received: April 25, 2001

Dear Dr. Estrin:

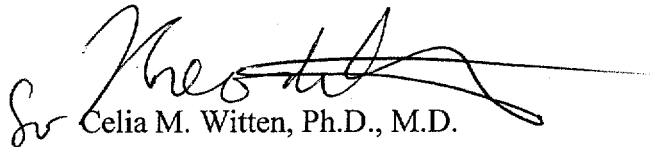
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K011262

Device Name: BOLD® SCREW

Indications for Use:

The "new" BOLD® SCREW is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Fixation of small bone fragments, in long bones or small bones fractures.
- Arthrodesis in hand or foot surgery
- Mono or Bi-cortical osteotomies in the foot or hand
- Distal or proximal metatarsal or metacarpal osteotomies
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)

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Concurrence of CDRH, Office of Device Evaluation (ODE):

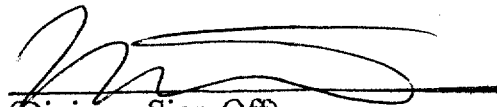
Prescription Use ☒

OR

Over-the-Counter
Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General, Regenerative
and Neurological Devices

510(k) Number K011262